



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
-----------------	-------------	----------------------	---------------------	------------------

10/584,510

05/14/2007

Robert Johan Joseph Hageman

0470-061930

4164

28289 7590 06/21/2010

THE WEBB LAW FIRM, P.C.
700 KOPPERS BUILDING
436 SEVENTH AVENUE
PITTSBURGH, PA 15219

EXAMINER

FORD, ALLISON M

ART UNIT

PAPER NUMBER

1651

MAIL DATE

DELIVERY MODE

06/21/2010

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/584,510	Applicant(s) HAGEMAN, ROBERT JOHAN JOSEPH	
	Examiner ALLISON M. FORD	Art Unit 1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 17 March 2010.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 18-39 is/are pending in the application.
- 4a) Of the above claim(s) 34-39 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 18-33 is/are rejected.
- 7) ☒ Claim(s) 19 and 20 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>20071227</u> . | 6) <input type="checkbox"/> Other: _____ |

Art Unit: 1651

DETAILED ACTION

Election/Restrictions

Applicant's election without traverse of Group I, claims 18-33, in the reply filed on 3/17/2010 is acknowledged. Because Applicants did not elect Group II, a species election was not required.

Claims 18-39 are pending in the instant application, of which claims 34-39 are withdrawn from consideration pursuant to 37 CFR 1.142(b). Claims 18-33 have been considered on the merits.

Priority

Acknowledgement is made of the instant application being a national stage entry under 35 USC 371 of international application PCT/NL04/00910, having an international filing date of 12/24/2004, and further claiming priority under 35 USC 119(a)-(d) to European application 03079190.9, filed 12/24/2003. A certified copy of the foreign priority document is present in the application file.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 18-33 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims are directed to a composition comprising 14-1000 mg pantothenic acid or an equivalent thereof and one or more of at least 15 En% protein, hydrolyzed proteins or amino acids, at

Art Unit: 1651

least 32 - 40 En% carbohydrates and/or at least 18 - 25 En% lipids. Dependent claims define additional elements of the composition.

The issue at hand is recitation of the language "pantothenic acid *or an equivalent thereof*" (in claim 18), "cysteine *or one or more cysteine equivalents*," "nucleotides *or one or more nucleotide equivalents*," "folic acid *or one or more folic acid equivalents*," and "vitamin B6 *or one or more vitamin B6 equivalents*" (all in claim 23).

The application is considered to lack written description for the full scope of the invention of each of pantothenic acid *equivalents*, cysteine *equivalents*, nucleotide *equivalents*, folic acid *equivalents*, and vitamin B6 *equivalents*.

To satisfy the written description aspect of 35 U.S.C. 112, first paragraph, for a claimed genus of molecules, it must be clear that: (1) the identifying characteristics of the claimed molecules have been disclosed, e.g., structure or other physical and/or chemical properties, by functional characteristics coupled with a known or disclosed correlation between function and structure, or by a combination of such identifying characteristics; and (2) a representative number of species within the genus must be disclosed. See *Eli Lilly*, 119 F.3d at 1568, 43 USPQ2d at 1406.

There is found to be insufficient written description in the instant disclosure to adequately describe or define all equivalents of pantothenic acid, cysteine, nucleotides, folic acid and B6. While one of ordinary skill in the art recognizes the disclosed compounds, per se (i.e. pantothenic acid, cysteine, nucleotides, folic acid and B6), one would not immediately envisage all compounds which Applicants are including in the scope of "equivalents" thereof. Applicants have not disclosed what functional characteristic of any of pantothenic acid, cysteine, nucleotides, folic acid and vitamin B6 compounds must exhibit in order to be suitable as "an equivalent thereof" in the claimed composition, and thus one cannot readily determine what alternative compounds are included in the scope of the claimed genres. Furthermore, without disclosure of a specific function, there clearly is no disclosed correlation between

Art Unit: 1651

function and structure, wherein such a correlation between structure and function is necessary to define a genus of chemical compounds, See *Enzo Biochem*, 323 F.3d at 964, 63 USPQ2d at 1613. An adequate written description of a chemical invention also requires a precise definition, such as by structure, formula, chemical name, or physical properties, and not merely a wish or plan for obtaining the chemical invention claimed. See, e.g., *Univ. of Rochester v. G.D. Searle & Co.*, 358 F.3d 916, 927, 69 USPQ2d 1886, 1894-95 (Fed. Cir. 2004). Therefore, it is not clear which compounds are appropriately considered "equivalents" of each of pantothenic acid, cysteine, nucleotides, folic acid and vitamin B6 which are to be included in the scope of the claim, and which are not.

Thus all claims are properly rejected under 35 USC 112, first paragraph.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 18-33 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 18 is interpreted as being directed to a composition comprising:

a) 14 - 1000 mg of pantothenic acid or an equivalent thereof, wherein the equivalent of pantothenic acid comprises at least 0.064 moles (0.064 being the number of moles in 14 mg pantothenic acid); and

b) and one or more of:

(i) at least 15 En% protein, hydrolyzed proteins or amino acids;

(ii) at least 32 - 40 En% carbohydrates; and

(iii) at least 18 - 25 En% lipids

Art Unit: 1651

wherein the composition has a caloric value of at least 100 kcal to about 1200 kcal.

Claim 18 is found indefinite because it is not clear how much "pantothenic acid equivalent" may be provided, 14-1000 mg of the pantothenic acid equivalent, or at least 0.064 moles of the pantothenic acid equivalent? These are not equivalent ranges. For example, "an equimolar amount of *at least* 14 mg of pantothenic acid" does not have an upper limit, thus, (because 14 mg of pantothenic acid is 0.064 moles), this limitation encompasses anywhere from 0.064 to (infinity) moles of a pantothenic acid equivalent. Alternatively, any salt of pantothenic acid will necessarily have a higher molecular mass than pantothenic acid, and thus 14 mg of the salt of pantothenic acid (as included in the range "14-1000 mg of pantothenic acid or equivalent thereof") will be less than 0.064 moles ("an equimolar amount of at least 14 mg of pantothenic acid"). Correction is required.

Furthermore it is unclear if the text provided in parenthesis "at least 15 En% proteins (*or hydrolysed proteins or amino acids*)" is intended to be part of the claimed invention, i.e. as examples of proteins, or if they are to be read as alternatives to proteins? See MPEP § 2173.05(d). The claim is therefore indefinite.

All dependent claims 19-33 inherit the deficiencies of claim 18, and therefore are rejected on the same basis.

Claim 21 is confusing because it is unclear if Applicants are requiring the composition of claim 18 to comprise at least one of:

1.8-6 g methionine,
5.8-12.0 g lysine,
1.5-4.0 g tryptophan, and
at least 8.0 g leucine.

Art Unit: 1651

Or if Applicants are intending to require the composition of claim 18 to comprise at least 15 En% protein, and wherein *the protein content* must comprise at least one of:

1.8-6 wt% methionine (1.8-6 g methionine/100 g amino acids);

5.8-12 wt% lysine,

1.5-4.0 wt% tryptophan, and

at least 8 wt% leucine,

so that the final composition comprises at least one of:

(at least 15 En% protein) x (1.8-6 wt% methionine),

(at least 15 En% protein) x (5.8-12 wt% lysine),

(at least 15 En% protein) x (1.5-4.0 wt% tryptophan), and

(at least 15 En% protein) x (at least 8 wt% leucine).

Claim 22 is held indefinite because it is not clear if the serine and glycine, provided in a ratio of 3.4 or higher must be provided *in addition* to the at least 15 En% protein, (i.e. "*further* comprising...") or if the serine and glycine provided in a ratio of 3.4 or higher are part of the protein content of the composition.

Similarly, in claim 23 it is unclear if the 0.2-5 g cysteine is provided *in addition* to the at least 15 En% protein, or if the 0.2-5g cysteine is part of the protein content of the composition.

Furthermore, in claim 23 it is unclear if "(1-10 g yeast, cytidine, uridine, nucleosides) is a claim limitation, or if it is an example of a nucleotide equivalent (in which case the range of 1-10 g does not correlate with the recited range of 0.2 to 5 g of nucleoside equivalents).

Art Unit: 1651

Furthermore, in claim 23 pantothenic acid cannot be (R)-pantoate. Pantothenic acid is distinct from (R)-pantoate. It appears the claim intended to recite "when the pantothenic acid *equivalent* is (R)-pantoate."

Claims 24-26 are rejected as indefinite because the scope does not correspond with that of parent claim 18. Claim 18 defines the composition as having a caloric value of 100 to 1200 kcal; however, claims 24-26 define the composition as having a caloric value of *at least* 600 kcal, 900 kcal and 1200 kcal, respectively. Claims 24 and 25 (which define a caloric value of at least 600 kcal and at least 900 kcal) are broader in scope than the parent claim, because neither of these ranges have upper limits. Claim 26 fails to correlate at all with parent claim 18 because it defines the caloric composition outside the range permitted by claim 18.

Claims 27-32 are indefinite because they require the composition to *further* comprise lipids in specified amounts, however it is unclear if the recited amounts are to be in addition to the at least 18-25 En% lipids which are recited in claim 18.

Claim 32 is further rejected because there is no requirement that the composition comprise any fatty acids, thus it is not clear claim 32 is further limiting the parent claims.

Claim 33 is rejected as indefinite because the scope does not correspond with parent claim 18. Claim 18 defines the composition as optionally comprising lipids in an amount of at least 18 En% lipids *up to* 25 En% lipids; 25 En% lipids is the upper limit provided by claim 18, thus claim 33 cannot require the composition to comprise *at least* 25 En% lipids, as this is outside the scope of the parent claim. Similarly claim 18 defines the composition as optionally comprising carbohydrates in an amount of at

Art Unit: 1651

least 32 En% *up to* 40 En% carbohydrates; 40 En% carbohydrates is the upper limit provided by claim 18, thus claim 33 cannot require the composition to comprise *at least* 40 En% carbohydrates, as this is outside the scope of the parent claim.

Claim Objections

Claims 19-20 are objected to for minor informalities:

In claim 19 the claim should technically define the proteins as being selected from the group consisting of "plant *proteins*, vegetable *proteins*, cereal *proteins*, seed *proteins* and whey *proteins*."

Correction is required.

Similarly, in claim 20 the language should read, "wherein the whey *protein* is acidic whey *protein*."

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

The claims are interpreted as being directed to a composition comprising:

a) 14-1000 mg pantothenic acid or an equivalent thereof; and

b) at least one additional component selected from the group consisting of:

Art Unit: 1651

(i) protein in an amount such that the proteins provide at least 15% of the total caloric value of the composition;

(ii) carbohydrates in an amount such that the carbohydrates provide 32-40% of the total caloric value of the composition; and

(iii) lipids in an amount such that the lipids provide 18-25% of the total caloric value of the composition; and

wherein the composition has a total caloric value of at least 100 kcal to about 1200 kcal.

Please note that "En%" is being interpreted as the percentage of energy, in the form of calories, provided by each of the recited components; this is the best interpretation that can be determined given the information in the specification.

Furthermore, please note that the intended use of the composition "stimulation of appetite in humans" recited in the preamble is only considered in so far as the composition must be administrable to humans. See MPEP 2111.02.

Finally, though the claim states the composition is provided in a 'daily dosage form' because the claim fails to define the daily dosage form by any size, volume, formulation, etc, the term 'daily dosage form' is not given patentable weight. Thus, the composition may have any size or form, so long as the total composition has a caloric value in the range of 100 kcal to about 1200 kcal.

Claims 18, 21, 24 and 25 are rejected under 35 U.S.C. 102(b) as being anticipated by Larson et al (US Patent 4,497,800), in light of Priya Chemicals "Amino Acid Composition."

*Please note that Priya Chemicals is relied upon solely for disclosure of inherent features (i.e. a 'universal fact') of a composition taught by the prior art. References relied upon solely for disclosure of universal facts need not be available as prior art before applicant's filing date. See *In re Wilson*, 311 F.2d 266, 135 USPQ 442 (CCPA 1962).

Art Unit: 1651

Larson et al disclose a liquid nutritional substitute food composition, the ingredients (with amounts) are listed at col. 6, ln 55-col. 7, ln 28). The amounts listed are for 10 L of the composition. For purposes of this rejection, 1 L of the composition is being relied upon as "a daily dosage."

Larson et al disclose 64 oz provides 2000 calories (kcal) (See Larson et al, col. 6, ln 7-11); thus 1 liter contains 1056 kcal $((2000 \text{ kcal})/(64 \text{ oz}) \times (33.814 \text{ oz})/(1\text{L}) = 1056 \text{ kcal/L})$ (claims 24-25).

One liter of the composition comprises 18.1 mg calcium pantothenate, 46.44 g protein, 3.269 g fat (lipids), and 216.89 g carbohydrates.

Regarding energy percentages:

Component	Amount in 1 L (g)	Energy Provided (kcal/g)	Energy Provided by Component (kcal)	Energy % (of 1056 kcal total)
Protein	46.44	4	185.76	17.2%
Fat	3.269	9	29.421	2.7%
Carbohydrate	216.89	4	867.56	80.1%

Thus, the protein provides 17.2% of the energy in the form of calories of the composition; 17.2% is greater than 15%, and therefore 1 liter of the composition anticipates the subject matter of claim 18.

The protein is provided as 45.3 g casein hydrolysate, 0.542 g methionine, 0.427 g tryosine, and 0.179 g tryptophan (per 1 liter).

Regarding amino acid composition of the protein component:

From Casein:

Amino Acid	Grams amino acid/100 g casein hydrolysate*	Total Casein Hydrolysate in 1 liter of composition (g)	Total Amino Acid content in 1 liter of composition (g)
Methionine	1.72	45.3	0.779 g/L
Tryptophan	1.23	45.3	0.557 g/L

*Data from Priya Chemicals

Regarding amino acid composition of the protein component:

Amino Acid	Source	Total in 1 liter	Wt% Amino	Grams amino acid/100
------------	--------	------------------	-----------	----------------------

Art Unit: 1651

			of Composition (g)	Acid content in 1 liter composition(%)	grams total amino acid (g/100g)
	Casein Hydrolysate (g)	Free Amino Acid (g)			
Methionine	0.779	0.542	1.321	2.84	2.84 g/100g
Tryptophan	0.557	0.179	0.736	1.58	1.58 g/100g

Thus, methionine is present at an amount of 2.84 g of methionine/100g amino acids in the composition; 2.84g/100g is within the range claimed in claim 21. Furthermore, tryptophan is present at an amount of 1.58 g/100g amino acids in the composition; 1.58 g/100 g is within the range claimed in claim 21.

Therefore the composition of Larson et al anticipates the subject matter of claims 18, 21, 24 and 25.

Claims 18, 19, 21, 23-25 and 27 are rejected under 35 U.S.C. 102(e) as being anticipated by Verheul-Koot et al (US Patent 6,846,494), in light of Kirkman Labs.

*Please note that Kirkman Labs is relied upon solely for disclosure of inherent features (i.e. a 'universal fact') of a composition taught by the prior art. References relied upon solely for disclosure of universal facts need not be available as prior art before applicant's filing date. See *In re Wilson*, id.

Verheul-Koot et al disclose a nutritional booster composition that can be provided in the form of a drink (See Verheul-Koot et al, col. 5, Example 2. Though Verheul-Koot et al disclose a dosage of 400 mL of the drink per day, for purposes of this rejection 800 mL of the drink is being considered "a daily dosage" which reads on the instant claimed invention, again noting that there is no limitation as to size or volume of 'daily dosage' of the claimed composition.

Art Unit: 1651

The ingredients included in 400 mL of the drink composition are listed in Table 1 at columns 4-5; because 800 mL of the drink composition is being relied upon, all values are doubled from what is listed in the table.

800 mL of the drink composition provides 1000 kcal energy, and comprises 16 mg pantothenic acid and 12 mg of vitamin B6 (See Verheul-Koot et al, Table 1)

Regarding energy percentages:

Component	Amount in 800 mL (g)	Energy Provided (kcal/g)	Energy Provided by Component (kcal)	Energy % (of 1000 kcal total)
Protein	80	4	320	32.0%
Fat	28	9	252	25.2%
Carbohydrate	112	4	448	44.8%

Thus, the protein provides 32.0% of the energy in the form of calories of the composition and therefore 800mL of the composition anticipates the subject matter of claims 18 and 23-25.

Regarding the protein content:

Verheul-Koot et al states arginine-rich peptides, such as pea proteins, may be used as the protein source (See Verheul-Koot et al, col. 2, ln 23-28). Pea protein is an plant and vegetable protein (claim 19).

Pea protein has the following amino acid content per 100 g protein:

Regarding amino acid composition of the protein component:

Amino acid	Grams of amino acid/100 grams Pea Protein*
Lysine	6.82 g
Leucine	8.44 g

*Data from Kirkman Labs

Thus, lysine is present at an amount of 6.82 g of methionine/100g amino acids in the composition; 6.82g/100g is within the range claimed in claim 21. Furthermore, leucine is present at an

Art Unit: 1651

amount of 8.44 g/100g amino acids in the composition; 8.44 g/100 g is within the range claimed in claim 21.

Regarding the fat content:

In 800 mL of the drink composition 28 g of fat (lipids) are provided; the total weight of 800 mL of the drink composition is 242.04 g (See Verheul-Koot et al, Table 1); thus the fat constitutes 23 wt%, which is equivalent to 23 g of fat (lipids) per 100 g of the composition (claim 27).

Therefore 800 mL of the drink composition of Verheul-Koot et al anticipates the subject matter of claims 18, 19, 21, 23-25 and 27.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 18-25 and 27-32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Larson et al (US Patent 4,497,800), in light of Reid et al (US 2009/0124551) and Virgin Coconut Oil "Fatty Acid Composition of Virgin Coconut Oil."

*Please note that each of Reid et al and Virgin Coconut Oil are relied upon solely for disclosure of inherent features (i.e. a 'universal fact') of a composition taught by the prior art. References relied upon solely for disclosure of universal facts need not be available as prior art before applicant's filing date. See *In re Wilson*, id.

Art Unit: 1651

The teachings of Larson et al are set forth above. Generally Larson et al discloses a nutritional composition which, in 1 liter, comprises 18.1 mg calcium pantothenate, 46.44 g protein (providing 17.2 En% of the composition), 3.269 g fat (lipids), and 216.89 g carbohydrates, and provides 1056 kcal (See Larson et al, col. 6, ln 7-11 & Table spanning from col. 6, ln 55-col. 7, ln 28).

Regarding the protein source:

Larson et al exemplify utilizing casein hydrolyzate as the protein source in the composition; however Larson et al state that a variety of protein sources may be utilized, and disclose casein, lactoalbumin, and soybean protein as alternatives to one another (See Larson et al, col. 5, ln 15-20). (Please note lactoalbumin is a whey protein).

Therefore, because Larson et al suggest that the protein component can be derived from alternative sources, and specifically suggest lactoalbumin, which is a whey protein, it is submitted that it would have been *prima facie* obvious to one having ordinary skill in the art to substitute whey protein for casein hydrolysate in the composition taught by Larson et al.

Whey protein (including acidic whey protein) comprises the following amino acids:

Amino acid	Grams of amino acid/100 grams Pea Protein*
Lysine	6.64 g
Serine	6.22 g
Glycine	1.34 g

*Data from Reid et al (Table 1)

Thus, lysine is present at an amount of 6.82 g of methionine/100g amino acids in the composition; 6.82g/100g is within the range claimed in claim 21. Furthermore, serine and glycine are present in a ratio (serine:glycine) of 4.64, which is within the range required by claim 22).

Therefore, substitution of acidic whey protein for the casein hydrolysate renders the composition of claims 21 and 22 *prima facie* obvious.

Art Unit: 1651

Regarding the fat content:

Larson et al exemplify including 3.269 g fat, comprised of 3.096 g of safflower oil and 0.173 g of soy oil, in one liter of the composition. This fat amount only constitutes 1.17 wt% of the composition, which is equivalent to 1.17 g lipids/100 g of the composition (based on a total weight of 278.45 g/L of the components set forth in the table at col. 6-7, excluding added water).

This value is slightly lower than the value claimed for the instant invention. However, it is noted that Larson et al teach that the fat component can range from 1.5 to 10 g of fat per liter of the composition (See Larson et al, col. 5, ln 35-37). Increasing the fat component from 3.269 g/L to 10 g/L in the composition set forth in the table at columns 6-7, would increase weight percent of the fat (lipid) component to 3.5 wt% (10 g fat/285.18 g/L (total weight, accounting for added 6.731g of fat (to go from 3.269 to 10 g of fat). A fat concentration of 3.5 wt% is equivalent to 3.5 g lipids/100g of the composition. 3.5 g is within the range set forth in claims 27-29.

Modification values of specific components within ranges disclosed by the same reference which discloses the composition is held to be *prima facie* obvious. Therefore, increasing the fat component to 10 g/L, which would provide 3.5 g lipids/100 g of the composition would have been *prima facie* obvious.

Furthermore, though Larson et al exemplify safflower oil and soy oil as the fat sources, they teach a variety of fat sources can be used and list safflower oil, soybean oil, corn oil, cottonseed oil, coconut oil, and olive oil as possible alternatives (See Larson et al, col. 5, ln 29-40). Therefore, because Larson et al suggest that coconut oil may be used as an alternative fat source than safflower or soybean oil, it is submitted that it would have been *prima facie* obvious to one having ordinary skill in the art to substitute coconut oil for safflower oil in the composition taught by Larson et al.

Art Unit: 1651

Coconut oil contains 92 wt% saturated fatty acids, which is equivalent to comprising 92 g of saturated fatty acids per 100 g of lipids. Coconut oil contains 16.8-21 wt% myristic oil, which is equivalent to 16.8-21 g of myristic oil per 100 g of lipids (See Virgin Coconut Oil). These values for coconut oil content satisfy the limitations of claims 30-32.

Therefore the invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ALLISON M. FORD whose telephone number is (571)272-2936. The examiner can normally be reached on 8:00-6 M-Th.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Allison M. Ford/

Application/Control Number: 10/584,510

Page 17

Art Unit: 1651

Primary Examiner, Art Unit 1651